



# UNITED STATES PATENT AND TRADEMARK OFFICE

*clh*  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,726	04/30/2001	George Jackowski	2132.033	3809

21917 7590 12/08/2006

MCHALE & SLAVIN, P.A.  
2855 PGA BLVD  
PALM BEACH GARDENS, FL 33410

EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
----------	--------------

1641

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/845,726

**Applicant(s)**

JACKOWSKI ET AL.

**Examiner**

Bao-Thuy L. Nguyen

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 36-43 is/are pending in the application.
- 4a) Of the above claim(s) 36-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Amendment*

1. Applicant's amendment filed on 30 September 2005 has been received. Claim 1 is pending. Claims 2-35 have been cancelled. Claims 36-43 are withdrawn.
2. All rejections not reiterated herein below are withdrawn in view of the amendment and/or cancellation of the claims.

### *Claim Rejections - 35 USC § 112*

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

SEQ ID NO. 1 has been amended such that it does not find support in the specification as originally filed. An amendment filed on April 25, 2002 deleted the amino acid (Ala His Lys Ser Glu Val Ala His Arg Phe Lys) listing in the specification and replaced it with SEQ ID NO. 1; subsequently, an amendment filed May 6, 2002 discloses a peptide consisting of 11 amino acid residues as SEQ ID NO. 1 (Ala His Lys Ser Glu Val Ala His Arg Phe Lys). These changes are proper and were entered. However, SEQ ID NO. 1 was modified in paper no. 13, filed on June 16, 2003 to be a peptide consisting of 12 amino acid residues with the first and last residues in

parentheses indicating predicted amino acids, this indicates that the invention is different from what is defined in the claim(s) and the originally specification because nothing in the specification leads one to predict that the peptide comprises 13 amino acids with the first and last being Asp.

*Claim Rejections - 35 USC § 101*

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. The claimed invention is directed to non-statutory subject matter. Claim 1 reads on a naturally occurring protein. It is suggested that applicant inserts either –isolated – or –synthetic–, if the protein is synthetic, between “a” and “biopolymer” for clarity.

6. Claim 1 is also rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claimed biopolymer marker peptide is not supported by either a specific and substantial asserted utility or a well established utility because the specification fails to assert any utility for the peptide. The specification as filed does not disclose or provide any evidence that points to an activity for the peptide. While the specification discloses conventional protein isolation techniques, it does not include any working examples of the characteristics of the isolated peptide or how to use it in a real world application.

Therefore, it is reasonable to conclude that the utility would not be credible based on the evidence of record. A well established utility is a specific, substantial and credible utility which is well known, immediately apparent or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. A well established utility is not any utility that one can dream up for an invention or a nonspecific utility that would obviously apply to virtually every member of a very general class of materials, such as proteins or DNA.

#### ***Claim Rejections - 35 USC § 112***

7. Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

#### ***Double Patenting***

8. The provisional rejection of claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09/846,347 is withdrawn in view of the abandonment of the co-pending application.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Bar-Or et al., (WO 01/25265).

Bar-Or discloses a peptide consisting of SEQ ID NO 4 (Ala His Lys Ser Glu Val Ala His Arg Phe Lys) useful for inhibiting the production of ROS. See page 43.

***Response to Arguments***

11. No arguments with respect to the art rejection, the 112 rejections or the 101 rejections were presented.

***Conclusion***

12. No claim is allowed.


13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**14.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641  
11/30/06